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Fred Hutchinson Cancer Research Center

Consent to take part in a research study:

**Pilot Randomized Study of a Proactive Financial
Navigation Intervention in Patients with Newly
Diagnosed Gastric and Gastroesophageal Junction
(GEJ) Adenocarcinoma**

Short Title: The Gastric Financial Navigation Study

Patient Consent

Principal Investigator: Veena Shankaran MD, MS. University of Washington; Fred
Hutchinson Cancer Research Center. Telephone: 206-667-7844

Important things to know about this study.

You are invited to participate in a research study. The purpose of this research is to look at whether a program designed to help people understand cancer care costs and access resources to help with medical and non-medical expenses while receiving cancer care will help gastric and gastroesophageal junction (GEJ) cancer patients and their caregivers in comparison to a group that does not receive this program. This program is called a “financial navigation program” because the intent is to help patients and caregivers through the financial aspects of cancer care.

We will enroll 30 patients and 30 caregivers in this study. This is a randomized study, which means that there are two possible groups that you could be assigned to: the “intervention group (otherwise known as the financial navigation program)” or “usual care.” You will be assigned to a group from a computer system and have a 50% chance of being assigned to either group. You may choose a caregiver to participate in the study with you, but caregiver participation is not required, and you may still join the study without a caregiver. If you choose to participate with your caregiver, you and your caregiver will be assigned to the same group. Your caregiver may be an unpaid, informal care-taker (such as your spouse, family member, or friend) who may or may not live in the same household as you. If you agree to join the study and are assigned to the intervention group, you will be provided with a resource list of agencies that may be of assistance to you, given the opportunity to watch a series of 6 short videos about financial navigation and participate in monthly phone calls over three months with our community-based partners who will provide education about and resources to help with cancer care costs. The videos are 3-20 minutes in length and cover different topics related to the financial aspects of cancer care. If you are assigned to the usual care group, you will not

receive the monthly phone calls. You will, however, be provided with a resource list and will be given access to the series of educational financial navigation program videos about cancer care costs. Regardless of which group you are assigned to, you will also fill out three surveys that will ask questions about your financial experiences and your quality of life. One survey will be completed after you consent to participate, one will be completed in three months and one in six months. You are also free to access any financial programs offered by your community or where you receive your cancer treatment.

You do not have to join this study. Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

We would like you to join this research study.

We are doing a research study to examine the potential impact of a financial navigation program for cancer patients and their caregivers. We want to know if a program designed to help people with their finances will help gastric and gastroesophageal junction (GEJ) cancer patients and their caregivers to understand cancer care costs and access resources to help with medical and non-medical expenses while receiving care related to a cancer diagnosis.

Since you are a gastric or GEJ cancer patient undergoing treatment, we would like to ask you to join this study. We will enroll up to 60 people.

If you agree to be in this study, we will do the following:

- **Surveys:** There are three surveys that you will complete during this study. One survey will be completed after you sign consent, or you may complete it online at home. There will also be a survey to complete in three months and again in six months. These surveys can be completed in person at a clinic visit, or at home through an online survey or over the phone with a study staff member. The surveys will take about 15-20 minutes to complete.
- **Medical Record Review:** The research study team will access your medical record at Seattle Cancer Care Alliance (SCCA) to look at clinical factors related to your cancer diagnosis and treatment. Insurance information and demographic information such as age, race, and gender will also be collected from your medical records.
- **Financial Literacy Video:** You will be offered the opportunity to view a series of online videos that explain basic healthcare coverage and financial concepts in healthcare.
- **Phone Calls:** If you are randomized to receive the financial navigation program, you and your caregiver will complete three monthly calls with each of our community partners, which are explained in further detail below. The confidential information shared in these meetings will be documented in a secure data

collection and will only be accessed by the research study team and our community partners.

- Receive monthly financial counseling via phone or video conference from coaches at Consumer Education and Training Services (CENTS). During these calls, you will be asked to share your confidential financial information with CENTS counselors. CENTS counselors will review the information you provide, work with you to develop a financial plan and provide other appropriate financial counseling services as needed. The first meeting will last approximately 75 minutes. Thereafter, sessions may take 75 minutes or less.
- Consult monthly by phone or videoconference with patient navigators at the Patient Advocate Foundation (PAF) who will work with you to provide access to available financial resources such as copayment assistance and if needed intervene on your behalf in an effort to resolve matters related to medical debt crisis, job retention/disability assistance and health insurance issues. The duration of these calls will depend on how much assistance you need. We estimate they will take less than one hour per month.

You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty or loss of benefits for saying no or dropping out. Whatever you decide, your regular medical care will not change.

If you leave the study, your survey results and information cannot be removed from the study records.

What are the risks?

The risks of this study are minimal. However, the questions that we or CENTS and PAF representatives ask about your financial experiences are sensitive and may make you feel uncomfortable. There is a small risk of loss of confidentiality.

What are the benefits?

This program has the potential to help Gastric and GEJ cancer patients and their caregivers understand cancer care costs and access resources to help with medical and non-medical expenses during a cancer diagnosis. Results from this study could motivate other oncology practices to include financial navigation as part of care as well as inform policy decisions around cancer care costs.

Protecting your Privacy as an Individual and the Confidentiality of Your Personal Information

Some organizations may need to look at your research records for quality assurance or data analysis. These include:

- Researchers involved with this study.
- The study sponsors, National Comprehensive Cancer Network (NCCN), and Eli Lilly Company
- Fred Hutchinson Cancer Research Center, University of Washington, and Seattle Cancer Care Alliance.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Research Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- Financial coaches at CENTS and patient navigators at PAF.
- Office for Human Research Protections

We will keep your records confidential. Your financial information will only be accessed by authorized study team members, patient advocates/counselors at PAF and CENTS, or the parties mentioned above. Information will be stored securely on a password-protected REDCap database set up by Fred Hutch.

However, we cannot guarantee total confidentiality. Your personal information may be given out if required by law. We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

How did you get my name?

We are studying patients from the Seattle Cancer Care Alliance and University of Washington. The doctor treating you thinks you may be eligible for this study.

Do I have to participate in the whole study?

Each part of the study is completely voluntary. You may choose to join all, some, or none of the study activities. You may stop the telephone conversations with CENTS and PAF at any time or choose not to answer some questions.

Will you pay me to be in the study?

As a token of thanks for your time and effort, you will be provided with a gift card, in the amount of \$25, after you complete the 6-month survey. Your caregiver, if they choose to participate in the project, will also receive a \$25 gift card when they complete their 6-month survey.

How much will the study cost me?

There are no costs for being in this study. The CENTS counseling sessions and assistance from PAF will be provided free of charge.

What will my information be used for?

Your information will be used for the purposes of this study.

Other information.

If you have questions or complaints about this study, please call Dr. Veena Shankaran at 206-667-7844. If you have questions about your rights as a research participant, call the Director of the Fred Hutch Institutional Review Office at 206-667-5900 or email irodirector@fredhutch.org.

Signature

Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

Participant:

Printed Name

Signature

Date

Please enter your preferred contact method: ☐ Telephone ☐ Email ☐ No Preference

Telephone Number: _____ ☐ home ☐ cell/mobile

Best time of day to call you: _____ ☐ am _____ ☐ pm

Email address: _____

Protocol: 3.0

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Copies to: Patient, file